FINAL DRAFT , WG 2, 1/30/04

National Aquatic Animal Health Task Force - Meeting Report of Work Group 2

"Diseases/pathogens of regulatory significance and their surveillance "

SeaTac Holiday Inn, Seattle, WA. January 15-16, 2004

Introduction:

The National Aquatic Animal Health Task Force (*Task Force*) has been charged by the Joint Subcommittee on Aquaculture (JSA) to develop a national aquatic animal health plan (NAAHP). The purpose of NAAHP is to: provide safe, efficient, and predictable commerce for aquatic animals; protect farmed and wild aquatic animals from the import of foreign animal diseases and pests; meet the United States' national and international aquatic animal health legal obligations; and, ensure the availability of diagnostic and certification services for private, public, and tribal aquaculture. The Task Force decided to develop the various elements of the plan in a transparent and collaborative process with its many stakeholders. The Task Force will convene work groups, which represent a broad spectrum of experts, to provide input on the various topics/elements of NAAHP. The work groups are informal in structure and are not advisory groups nor are they operating under the rules of FACA. Discussions of the work groups will be captured in meeting reports such as this one. These reports will in turn be used to develop draft chapters of the plan. After approval by the Task Force, the draft chapters will be submitted to JSA and our stakeholders for comment. Eventually, the finalized chapters will be adopted by the Task Force as part of NAAHP.

Work Group 2 (WG 2), met on January 15-16, 2004, in Seattle, Washington. The purpose of WG 2 was to identify the diseases/pathogens of regulatory significance in the US and discuss surveillance programs which monitor for their occurrence. It is understood that OIE standards and most aquatic regulatory programs consider diseases and the pathogens that cause them to be synonymous for regulatory purposes. WG 2 recognized the urgency to proceed with the identification of regulatory pathogens, surveillance schemes, and establish "specific disease free-zones" in the US.

Participants:

Task Force: Marilyn Blair (USDI/FWS), Jill Rolland and Bronte Williams (USDA/APHIS), and Kevin Amos (DOC/NOAA Fisheries).

Stakeholders: Don Hoenig, American Veterinary Medical Association; Bruce Stewart, Northwest Indian Fisheries Commission; Andy Goodwin, University of Arkansas; Jim Winton, USGS; Steve Ellis, APHIS; Sharon MacLean, NOAA Fisheries; Jim Parsons, Troutlodge; and, Ralph Elston, Aqua Technics.

Discussion:

Day 1 - The first order of business was a welcome on behalf of the entire Task Force and introductions/backgrounds of the participants. Next, an explanation was given to WG 2 on the process of NAAHP development, process for identification of work group participants, and explanation of expectations of the work group. A proposed agenda was distributed and considered by the group (see attached - Agenda for WG 2). The group accepted the agenda as a guideline for deliberations.

Before proceeding with the discussions on diseases, one participant asked the question if resources are being obtained to implement NAAHP, or is the Task Force and stakeholders "wasting time" in developing the plan. The response from the Task Force members was that it is the intent and direction of the Federal agencies to support the development and implementation of a national plan. Stakeholders must recognize that the Federal budgeting process takes place two to three years in advance. Also, aquatic animal health must compete with other programs for funding, programs that may be perceived by administrators or politicians as having a higher priority. Nevertheless, by the commitment of the three federal agencies to date and plans to increase involvement, the Task Force has an expectation that the NAAHP will happen. The Task Force is optimistic in spite of the fact that until recent years, the track record of federal agencies has not been strong for the support of aquatic animal health activities. The group also recognized that work on obtaining funding must start now in anticipation of implementation in the not-too-distant future. If we do all the planning and only then start on the implementation strategy, the delivery date will be extended by another 2 to 3 years. It is recognized by all that industry and organizations such as USAHA, AFS, and AVMA will play large roles in enabling the NAAHP to be implemented.

WG 2 examined the OIE list of diseases and their criteria for listing. All participants were supplied with a copy (or brought their own) of the OIE Code for Aquatic Animals. (Thanks to APHIS for purchasing copies of the OIE Code!) While the OIE Aquatic Animal Standards Committee have proposed changes scheduled for implementation

January 1, 2005, the OIE criteria for listing of an OIE *notifiable* disease are as follows: a) Consequences - causes significant impact on production, wild resources, or human health; b) Spread - infectious etiology (or strongly suspected) and can spread via commerce; c) several countries are free of the disease; and, d) a repeatable, robust method is available for diagnosis.

WG 2 discussed two types of *notifiable* diseases in the US - those that are exotic and those that are endemic. While the term *foreign animal disease (FAD)* has a special meaning in APHIS parlance, we were not sure that is the way the US should label "exotic notifiables". WG 2 generally agreed with the criteria of the OIE and added criteria - the disease must involve species that are in commerce, interstate or international and be of concern to US trading partners. Obviously, for exotic notifiables, they must not occur in the US. For enzootic notifiables, they must have limited distribution in the US. We briefly discussed "pathogens of regional concern". WG 2 suggested that these types of organisms should be left to regional/local groups to deal with and not include them in a national plan, recognizing that if a regional group chooses to regulate a disease or pathogen, they must have a surveillance and control program in that region in place. In other words, they legally (under interstate commerce regulations and WTO) cannot restrict the entry of a aquatic animal infected with a pathogen unless there is an absence of that agent in their region and/or there is a control program which prevents the intra-region spread of that agent.

The lists of notifiable diseases are as follows and are restricted to specific species of finfish, crustaceans, and mollusks.(species affected by the specific diseases are not listed below). Diseases of other types of aquatic animals were not considered by WG 2.
Finfish - Exotic: OMV, EHNV, red sea bream iridovirus
Finfish - Enzootic: VHSV (all strains), ISAV, SVCV, IHNV, IPNV, and VER (Nodavirus).

Crustaceans - Exotic: Taura syndrome virus, Yellowhead virus, Spherical baculovirus, IHHN
Crustaceans - Enzootic: WSSV, Tetrahedral baculovirus, Aphanomyces astraci, NHP
(Notes on crustacean diseases provided by D. Lightner – IHHNV is enzootic on several oyster farms on Oahu, Hawaii, but has not been reported on US mainland. WSSVand tetrahedral baculovirus are enzootic in wild shrimp stocks in the Gulf of Mexico but have never been reported on US shrimp farms. Emerging shrimp disease IMN "infectious myonecrosis" found in NE Brazil qualifies for OIE notifiable but is not yet on the OIE list due to lack of publications on the condition.)

Mollusks - Exotic: Bonamia exitiosus, Marteilia refringens, M. sydneyi, M. roughleyi, M. chungmuensis, Perkinsus olseni/atlanticus
Mollusks - Enzootic: B. ostreae, M. mackini (consider removal when OIE does so), C. Xenohaliostis californiensis, QPX

A brief discussion was held on the opportunity for these pathogens to enter the environment from pathways other than live animals, for example, processing wastes or from organisms used for bait in commercial or recreational fisheries. This issue is a concern and needs to be addressed when developing species/disease-specific disease control programs. It was noted that there is a need for a group (s) of experts to meet annually to update these lists of pathogens, similarly to how the OIE Aquatic Animal Standards Commission operates.

The discussion next moved to surveillance and zonation. Preliminary points made - The US needs to zone by pathogen/species of animal; zones will be defined by surveillance scheme; It makes sense for a national plan, and to be consistent with international trends, to manage on a zone-basis rather than on a lot-by-lot basis, recognizing there may be needs for both and countries receiving imports form the US may still require inspections on a lot-by-lot basis; Is it possible to zone facilities that are not on pathogen-free water? The answer seems to be yes. As a sidebar, it was pointed out that, regardless of the pathogens we list as "emergency" or "FADs", as per disease-specific control programs, policies/rules must be in place such that we can act in a timely fashion, such as we have done for BSE or are ready to do in the event of FMD outbreak. Generally, federal programs such as these are not in place for aquatic animal diseases. WG 2 adjourned for the day.

Day 2 started with discussions on zonation. Ralph Elston provided a hypothetical example for zonation for mollusks on an open coastal water system. (Species - oysters; Disease of interest - M. mackini; Health history of site - 15 years of freedom under a surveillance program. Disease is known to occur in the state.) Can a zone be identified and maintained in such a scenario? The answer appears to be yes, contingent on hydrological movement of

pathogens, proximity of positive sites, surveillance schemes for cultured and wild oysters in the designated zone, control of imports into zone of certified stock, and willingness of trading partners to accept the designation of such a zone.

Economically, there is great value in identifying and maintaining zones as it can be quite expensive conducting inspection exams on a lot-by-lot basis as this approach may require the examination of 150 individuals twice a year. Finfish samples can be pooled to 5 fish /sample but histo-pathology for shellfish has to be done on an individual animals.

In the short term, the US may need to combine historical data with lot-by lot exams as this approach may still be required by our trading partners but a transition to a zonal approach makes sense.
WG 2 looked at the Pacific region as a "free-zone" for ISA. All evidence suggests that it is. Surveillance is needed on an ongoing basis to protect Pacific coast and to continue to be sure ISA is not present. ISA is known to occur in Maine but how far south is it known to occur? Rigorous monthly monitoring by facilities in Maine under the APHIS-ISA control program would indicate that it is not distributed state-wide...not much further south than Cobscook Bay, Maine. It is the role of the Competent Authority(ies) to declare a free-zone, in this case APHIS is in the lead with input from state and federal agencies. It is of note that the testing for ISA by the laboratories is being funded by APHIS under their ISA program, excluding the costs of sample collection. .

A need was identified, for all data gathered under a surveillance program, for a comprehensive database system. Two federal structures in place that might be useful for NAAHP are the NAAHMS and the FWS Wild Fish Survey.

While there is a model plan to deal with FADs for terrestrial animals, none is available for aquatic diseases. Need is there to transition into such a plan. As previously mentioned, also need to consider offal and wastes from aquatic animals and the potential entry and dissemination of pathogens with it.

Other diseases were considered. BKD (caused by R. salmoninarum) is widely distributed in the US and did not seem to fit the criteria for a notifiable disease nor did it seem that it should be a pathogen regulated for inter-state commerce. Whirling disease was briefly discussed. As it is widely distributed, it did not fit under the criteria for being notifiable. However, if states have control programs and can demonstrate absence or limited distribution, it may be possible to prevent the introduction of diseased fish into their state. IHNV was considered...it appears that east of the Rocky Mountains would be considered a "free-zone". While IHNV occurs in anadromous salmon stocks on the Pacific region, there are many facilities on SPF-water that are "free-zones". Again, states wishing to limit the movement of eggs/fish from a positive zone would have to demonstrate a control program is in place and distribution of agent is limited.

Another example considered was VHSV. While widely distributed in herring and other marine fish on the Pacific coast, distribution is limited in the Atlantic coast region. A recent finding in herring in Maine would indicate that the Atlantic coast is not a free-zone. In establishing zones for open water systems, consideration must also be given to the migratory patterns of potentially infected populations.

Surveillance schemes to establish free zones likely would require at least a 2 year period, or greater, depending on the life-cycle of the animal being considered (like salmon, which require 2-4 years to reach sexual maturity...the time at which some latent pathogens can be found). It may be necessary to start at the 2% level (150 animals) as per OIE. Federal assistance to fund sampling to establish surveillance zones would be helpful.

WG 2 identified the need to establish zones now - can't wait for entire NAAHP to be finished.
How to do this? APHIS/FWS/NOAA Fisheries working together could identify and declare "free-zones" based on historical data. We would start with the "easy ones" such as ISAV-free West Coast and IHNV-free east of the Rockies. Designation of zones must be comprehensive to the degree possible and include all watersheds and facilities possible. The zones could be published in CFR. The follow-up would be to maintain these zones via ongoing surveillance, data from the Competent Authorities in the US, states, and tribes with testing as per the Federal plan and in approved laboratories, i.e., APHIS-approved laboratories. The urgency to establish zones is occurring for some species groups due to new regulations being published by EU and other countries. The establishment of zones is also important now in order to facilitate inter-state commerce. The model being contemplated/developed for international commerce would be an appropriate approach to consider for interstate

commerce.

Summary of issues to consider for NAAHP:

- A list of federally notifiable diseases was developed for consideration for finfish, mollusks and crustaceans. Criteria were established for listing. Listing needs to be established by species. In other words, it cannot be scientifically supported to require inspection of a species in which the disease does not occur - for example, requiring that catfish be tested for IHN virus.
- Concern for the entry of notifiable pathogens in products other than live animals.
- Need for the Competent Authorities to be pro-active in developing emergency disease response programs. (Note* - these types of programs will be developed as components of other chapters of NAAHP, namely Chapter 6.)
- Other pathogens may be of regional concern but are not listed because they don't meet the national criteria, such as BKD or Whirling disease. Caution given to regions/states which place restrictions which may be non-tariff trade barriers.
- Zonation is the approach which the US needs to adopt.
- Need exists to establish a comprehensive federal database for the purposes of storing surveillance data and identifying "free-zones". Funding must be made available soon to support this database.
- While many surveillance programs are in place by private and government entities, support may be needed from the Federal government to kick-start some surveillance schemes.
- There is a need **now** to start the establishment and declaration of zones in the US. This will be a collaborative effort of the federal agencies of the Task Force. Concurrently, industry stakeholders should consider engaging the US Animal Health Association, Aquaculture Committee, for the purpose of developing appropriate resolutions.
- The Task Force needs to provide leadership in developing and implementing zone programs for both international and interstate commerce.
- The federal agencies need to make a continued and increasing commitment of resources in order to bring NAAHP to fruition.

Next steps:

Input from WG 2 will be used in drafting portions of Chapters 4 & 5 of NAAHP relating to diseases of concern, surveillance, and zonation. Draft portions of Chapters 4 and 5 will be completed sometime in 2004. At this time, there does not appear at this time a need to re-convene WG 2.

Feedback from participants (evaluation forms):

- Participants gave high marks to the Task Force for the organization, facilitation, and meeting the objectives of the workshop. They felt their time was well spent.
- Concerns were expressed re laboratory certification, involvement of NVSL, respecting the privacy of private companies in regard to testing results, and obtaining funding to accomplish the surveillance program.
- It might be helpful to expose workshop participants to hypothetical scenarios prior to the workshop in order to better prepare them for deliberations.
- As process for the workshops in general, it would be helpful if one of the facilitators summarized the comments from one session before moving on to another topic or session.
- It would be helpful to insert in the work books a flow chart which explains the process by which the efforts of working groups translates into elements of NAAHP.